

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

| | | |
|---|--|--|
| Applicant's or agent's file reference 700953-53661 | FOR FURTHER ACTION <small>see Form PCT/ISA/220 as well as, where applicable, item 5 below.</small> | |
| International application No. PCT/US04/37810 | International filing date (day/month/year) 12 November 2004 (12.11.2004) | (Earliest) Priority Date (day/month/year) 12 November 2003 (12.11.2003) |
| Applicant THERION BIOLOGICS CORPORATION | | |

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 5 sheets.



It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the Report**
 - a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
 - b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.
 - c. Certain claims were found unsearchable (See Box No. II)
 - d. Unity of invention is lacking (See Box No. III)
4. With regard to the title,
 the text is approved as submitted by the applicant.
 the text has been established by this Authority to read as follows:
5. With regard to the abstract,
 the text is approved as submitted by the applicant.
 the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.
6. With regard to the drawings,
 - a. the figure of the drawings to be published with the abstract is Figure No. _____
 as suggested by the applicant.
 as selected by this Authority, because the applicant failed to suggest a figure.
 as selected by this Authority, because this figure better characterizes the invention.
 - b. none of the figures is to be published with the abstract.

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Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.: 2 in part
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
Claim 2 is a multiple dependent claim that depends in the alternative on itself. As such, the claim has only been considered to the extent that it depends on claim 1.

3. Claims Nos.: 3 and 6-22
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

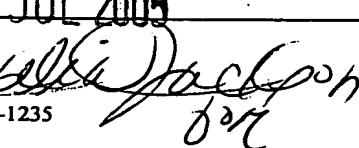
The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

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| A. CLASSIFICATION OF SUBJECT MATTER | | |
|---|---|---|
| IPC(7) : A61K 48/00; C12N 15/00, 15/63, 15/74, 5/00 US CL : 514/44; 435/320.1, 325, 455 | | |
| According to International Patent Classification (IPC) or to both national classification and IPC | | |
| B. FIELDS SEARCHED | | |
| Minimum documentation searched (classification system followed by classification symbols) U.S. : 514/44; 435/320.1, 325, 455 | | |
| Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched None | | |
| Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Please See Continuation Sheet | | |
| C. DOCUMENTS CONSIDERED TO BE RELEVANT | | |
| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| X | SCHOLL, S. et al. Metastatic breast tumour regression following treatment by a gene-modified vaccinia virus expressing MUC1 and IL-2. J. Biomed. & Biotech. August 2003, Vol. 3, pages 194-201, see entire document | 1-2, 4 |
| Y | | 5, 23-24 |
| X | AARTS, W.M. et al. Vector-based vaccine/cytokine combination therapy to enhance induction of immune responses to a self-antigen and antitumor activity. Cancer Research. 2002, Vol. 62, pages 5770-5777, see entire document. | 1-2, 4, 5 |
| Y | | 23-24 |
| Y | ZAJAC P. et al. Phase I/II clinical trial of a nonreplicative vaccinia virus expressing multiple HLA-A0201-restricted tumor-associated epitopes and costimulatory molecules in metastatic melanoma patients. Hum. Gene Ther. 2003, Vol. 14, No. 16, pages 1497-1510, see entire document. | 1-2, 4-5, 23-24 |
| X | SCHLOM, J. et al. Strategies for the development of recombinant vaccines for the immunotherapy of breast cancer. Breast Canc. Res. Treat. 1996, Vol. 38, pages 27-39, see entire document. | 1 |
| Y | | 2, 4-5, 23-24 |
| <input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> | | See patent family annex. |
| <p>* Special categories of cited documents:</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p> | | |
| Date of the actual completion of the international search | | Date of mailing of the international search report |
| 31 May 2005 (31.05.2005) | | 12 JUL 2005 |
| Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230 | | Authorized officer Anne Marie S. Wehbe  Telephone No. 703-308-1235 |

INTERNATIONAL SEARCH REPORTInternational application No.
PCT/US04/37810**C. (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|--------------|--|-------------------------------|
| X -- Y | WO 98/04727 (THERION BIOLOGICS CORPORATION) 5 February 1998 (05.02.1998), see entire document. | 1 _____ 2, 4, 5, 23, 24 |
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Continuation of B. FIELDS SEARCHED Item 3:
DIALOG-medicine database; BRS/EAST-USPatfull, EPO, JPO, Derwent, TJS-Pubs
search terms: vaccinia, poxvirus, nyvac, alvac, mva, wyeth, CEA, mucin, her-2/neu, muc-1, gm-csf, b7, tricom